

EXHIBIT A

**Declaration of Sharon Baucom, M.D.
with attached documents**

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

RANDY BUXTON #339322,

*

Plaintiff,

*

v.

*

Civil No. PJM-10-2211

SHARON BAUCOM, *et al.*,

*

Defendants.

*

* * * * *

DECLARATION

I, Sharon Baucom, M.D., am competent to testify to the following based on personal knowledge, and hereby declare under the penalty of perjury that the following is true and correct.

1. I am the Director of Clinical Services for the Maryland Department of Public Safety and Correctional Services ("DPSCS"). I have held that position for more than ten years. As Director, I am an administrator. I do not practice medicine or provide medical care to Maryland inmates. I do not prescribe or provide medications to individual inmates. I do not determine which individual Maryland inmates should be referred for review to determine whether they should receive antiviral treatment for Hepatitis C. I do not exercise supervisory authority over the employees of the private medical contractors.

2. I am familiar with the allegations made by inmate Randy Buxton # 339322. He is housed at the Western Correctional Institution ("WCI") in Cumberland.

3. After being informed of this lawsuit, I have reviewed pertinent medical information concerning Plaintiff. All documents attached to this Declaration are kept and maintained in the regular course of business of the DPSCS. Medical records were made at or near the time of occurrence of the matters recorded therein by a person or persons having personal knowledge of the matters recorded, or from information transmitted by such person or persons.

4. Physicians and other personnel employed by private medical contractors have actively treated Maryland inmates with Hepatitis C ("HCV") since 2005, using protocols developed and approved by a specialist in infectious diseases at the University of Maryland Institute of Human Virology, as well as specialists from Johns Hopkins University. To date more than 1800 inmates have been diagnosed with HCV, a virus specifically associated with high risk behaviors such as intravenous drug use. The course of this viral disease, and its impact on the liver, is asymptomatic and takes between 10 and 20 years to develop. Maryland's prison system is among the leading state correctional systems in the number of inmates who have been successfully treated using antiviral medications. The success of the DPSCS HCV treatment program has been cited by the legislative subcommittee on HCV in Annapolis.

5. Under the protocols it is the responsibility of the private medical contractors to identify inmates infected with HCV, review their cases against the protocols and guidelines, identify those inmates eligible for HCV antiviral treatment, and refer their cases

or be deferred. *See* Infection Control Manual, Medical Management of Hepatitis C, attached to this Declaration, pages 2 - 8.

6. The DPSCS review panel includes:

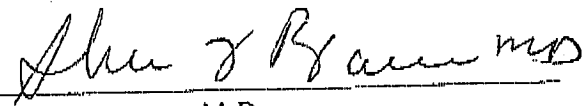
Director of Clinical Services (myself);
State-contracted UMMS Infectious Disease Specialist (Dr. Rufael);
State Director of Nursing;
State HCV Nurse;
Medical Contractor's Epidemiologist;
Medical Contractor's Regional Medical Directors;
Medical Contractor's Site Physicians (when indicated);
Medical Contractor's Registered Nurse;
Medical Contractor's Administrative Assistant; and
other participants as needed.

7. My role in the panel is to authorize payment to the medical contractors for the treatment and to provide insight into the policy and procedures that govern the process. The UMMS infectious disease specialist, Dr. Rufael, makes the decision to treat or defer treatment, including ordering a biopsy of the liver. I am not a specialist in infectious diseases and therefore rely on the medical judgment of the specialist. I have never over-ruled the specialist or substituted my judgment for his.

8. I did not become personally aware of Plaintiff's attempt to obtain antiviral treatment for HCV until after he filed this lawsuit. His case was presented by the medical contractor to a DPSCS panel for review for possible treatment on September 13, 2010. Due to Plaintiff having recently tested positive for opiate use, antiviral therapy was not indicated at that time. There is a very high likelihood of non-responsiveness to the antiviral medications if there is active use/abuse of illicit drugs. It was recommended that Plaintiff undergo drug rehabilitation treatment and that his case be reviewed again in six months. Antiviral treatment, therefore, was deferred.

I have read the above statements, and hereby declare under the penalties of perjury that they are true and correct.

Date: 1/21/11


Sharon Baucom, M.D.
Director of Clinical Services
DPSCS

Infection Control Manual

Medical Management of Hepatitis C

OFFICE OF PROGRAMS AND SERVICES:
CLINICAL SERVICES

INFECTION CONTROL MANUAL

Chapter 2
MEDICAL MANAGEMENT OF HEPATITIS

Section 3
HEPATITIS C

I. Policy:

Inmates who have been diagnosed with Hepatitis C virus (HCV) infection, shall undergo appropriate evaluation and treatment in accordance with current standards of medical practice. HCV infected inmates will be enrolled in chronic care clinics for education, medical evaluation and treatment.

II. Procedure:

A. HCV testing will be conducted where clinically indicated or in the presence of risk factors with or without elevated LFT including, but not limited to:

- 1.) HIV infection or chronic HBV infection.
- 2.) Signs or symptoms of acute or chronic hepatitis including elevated enzymes or jaundice.
- 3.) Percutaneous exposures to blood.
- 4.) Chronic hemodialysis which requires the clinician to screen ALT levels monthly and anti-HCV by immunoassay semi-annually.
- 5.) Risk factors as defined by CDC.

B. Pre-test counseling will occur so that inmates are provided with basic information regarding transmission, diagnosis and screening measures for HCV. During the counseling session, a Pre-test counseling form will be presented to the inmate for signature to indicate his understanding to testing. This will be documented on the HCV Evaluation Work Sheet.

- C. An HCV Evaluation Worksheet will be initiated by the nurse and/or clinician if Hepatitis C is suspected. A Hepatitis screening panel will be drawn and sent to the lab for analysis unless record review demonstrates previous/recent testing.
- D. Post-test counseling will be conducted, and documented, for all inmates who underwent HCV testing and will consist of:
 - 1.) Delivery of HCV basic information,
 - 2.) HCV lab results with basic interpretation of results, and
 - 3.) Possible options for further treatment with review of exclusionary criteria for antiviral treatment (for the inmates who are found HCV positive) .
 - 4.) Based upon the lab tests results (HCV positive vs. HCV negative) a Post-test counseling form will be presented to the inmate for signature to indicate his/her understanding of the process. This will be documented on the HCV Evaluation Work Sheet of the inmates who are tested HCV positive.
- E. A continued work up of detainees found to have Hepatitis C (HCV antibody positive) includes:
 - 1.) He/she will be enrolled in a Hepatitis Chronic Care clinic and is expected to be seen by a physician every 3 months. (Non-compliant cases that are mono-infected may be seen as infrequently as once a year; however this should not be encouraged and is not advisable. Such infrequent visits must be on the order of the clinician and requires documentation regarding the reason for the infrequency). Clinician will document return time frames for follow up visits in the progress notes.
 - a. The clinician will add the diagnosis to the Problem List in the medical record/EMR and will initiate a written Plan of Care (Treatment Plan).
 - b. At first chronic care visit, the clinician will document on the progress notes the antibody test results and provide further education about the management of HCV disease.

- c. The inmate will be given additional "Hepatitis C Virus: Fact Sheets/Education sheets," This will be documented on the HCV Evaluation Work Sheet
 - d. Screening for HIV status will be completed if the HIV Status is unknown. This will be documented on the HCV Evaluation Work Sheet, in EMR and the Problem List.
- 2.) During the first visit to Chronic Care Clinic which should be within 30 days of receipt of positive HCV test, detainee will start receiving vaccinations for Hepatitis A and B using a combination vaccine as appropriate. This will be documented on the Evaluation Work Sheet.
- a. Consent for immunization must be obtained and filed in the medical record.
 - b. The remainder hepatitis A and B immunizations will be completed during the inmate's visit to the hepatitis chronic care clinic visits per prescribed schedule.
 - i. Documentation of the administration of the vaccination shall be completed on the DPSCS immunization record.
 - ii. The DPSCS immunization record shall be maintained in the patient's medical record and documented in the EMR.
 - c. An alternative accelerated schedule may be used when the clinician feels it is medically appropriate and documents the need for the accelerated schedule.
 - ii. Only a recognized manufactured combination Hepatitis A and Hepatitis B may be used.
 - iii. The combined vaccine should be administered by intramuscular injection. It is never to be administered intradermally or intravenously.
 - iv. The combined injection should be given in the deltoid region and NOT in the gluteal region.
 - v. Primary immunization for adults consists of three (3) doses, given on a 0, 1 and 6 month schedule.

- vi. The alternative dosing is a four (4) dose schedule given on days 0, 7, and 21 to 30, followed by a booster at month 12.
- 3.) At first chronic care clinic and prior to additional testing, if the inmate has any of the following conditions, then he/she will not be eligible for antiviral therapy but will be enrolled in chronic care clinic for monitoring.
- a. Age <18, or age >60 years.
 - b. Life expectancy less than 10 years.
 - c. Remaining incarceration time <24 months for genotype 1 and HIV/HCV co-infected inmates and <12 months for genotypes 2 and 3 (provide release date)
 - d. History of solid organ transplant.
 - e. Known/documented history of autoimmune disease.
 - f. Known/documented compliance rate with any chronic care conditions/visits, and/or medication adherence <80%. (eg. Poor HgA1c, TLTBI RX, etc.)
 - g. Known/documented alcohol and/or illicit drug use within previous 12 months. (Check OMSR)
 - h. Pregnancy
 - i. AIDS (CD4 <200, VL >50,000 copies)
 - j. Decompensated liver disease
 - k. Decompensated mental health condition and non compliant with mental health medications/care plan.
 - l. Active, or history of, an Axis I, II, or III Psychiatric Diagnosis unless specifically approved by both Medicine and Psychiatry.

4.) If inmate does not have any of the above exclusionary criteria above then he/she will undergo additional testing.

5.) Detainees who are eligible for antiviral therapy will be provided with education regarding the HCV medical workup and the possibility that antiviral therapy may be needed. Detainee will sign the HCV Informed Consent Sheet to continue the workup. If the detainee agrees, the clinician will:

a. Obtain the following lab tests:

- i. Comprehensive chemistry to include at a minimum: albumin, bilirubin, CBC, creatinine, ALT, TSH, (HIV test with pre/post test counseling per AIDS Administration guidelines), PT-INR, AFP, ANA, Ferritin
- ii. If female, pregnancy test,
- iii. If known diabetic, Hg a1c.
- iv. Draw an HCV Viral Load and Genotype to determine chronic infection (vs. Clearance of the virus) and the type of the Hepatitis C virus.

b. Document the lab results on the HCV Initial Lab Flow Sheet.

6.) If detainee is found to have HCV present on viral load analysis, then general screening for antiviral treatment will occur. Documentation of baseline HCV VL and genotype will be placed on the HCV Initial Labs Flow Sheet, and clinician will write an order to place the inmate on Medical Hold using the appropriate form (DPSCS Form 130-100ir).

a. Clinician will obtain a mental health consultation for documentation and confirmation of an active, or history of, an Axis I or Axis II diagnosis and submit a Psychiatry Referral Form to the institutional psychiatrist for confirmation of an active, or history of, an Axis I or Axis II diagnosis.

b. Regional Infection Control Coordinator/designee will be responsible for the submission of a copy of the

completed psychiatry referral form to be included with the Hepatitis C Treatment Request packet to the DPSCS Medical Director's office with a copy to the Statewide Mental Health Director.

F. Upon receipt of the HCV genotype results, *within 14 days* the clinician will meet with the inmate and discuss/formulate HCV treatment plans that will include:

- 1.) An evaluation of laboratory results.
- 2.) Consultation Request for GI or ID specialist for all inmates being considered for liver biopsy or antiviral therapy should be requested within 30 days of treatment plan discussion post receipt of genotype
- 3.) Liver biopsy:
 - a. Inmates with genotype 2 or 3 will not be required to have a liver biopsy to be considered for HCV antiviral therapy.
 - b. HIV/HCV co-infected inmates will not be required to have liver biopsy prior to consideration of antiviral therapy. This exception can be waived at the request of the inmate.
 - c. All other categories will undergo liver biopsy unless the ID/GI specialist recommends for other clinical reasons an alternative assessment tool like fibrosure.
- 4.) Inmates' candidacy for antiviral HCV therapy.
The medical record, complete with all information recorded as stated shall be assembled and prepared by the Regional Infection Control Coordinator and the Statewide/Regional Medical Director or designee and forwarded to the DPSCS HCV coordinator prior to presentation to the HCV panel.
- 5.) The inmate shall be placed on a "medical hold."

G. If liver biopsy is a consideration prior to treatment, the clinician will present the case at the next scheduled DPSCS clinical panel telemedicine meeting to obtain approval for liver biopsy prior to a

request being sent to Utilization Management for approval and authorization, and:

- 1.) The presentation to the panel for liver biopsy must be done as outlined in the "Biopsy Request Process" form
- 2.) Once the clinical panel approves a liver biopsy, the medical provider will present the case to Utilization Management *within five days* of the panel approval determination.
- 3.) *Once approved, the liver biopsy will be scheduled and performed within 6 weeks of the UM approval date.* If not, the reason for delay will be documented in EMR and panel will be notified. Clinicians will follow the process as stated:
 - a. If the liver biopsy is normal or indicates minimal fibrosis – monitor and re-biopsy in three (3) years.
 - b. If the liver biopsy shows portal or bridging fibrosis and moderate inflammation and necrosis - consider antiviral therapy and monitoring in Chronic Care Clinic.
 - c. If the liver biopsy shows decompensated hepatic disease, the inmate will not be a candidate for antiviral therapy and detainee will be followed in Chronic Care Clinic with counseling regarding options including consideration for medical related parole.
 - d. If the inmate refuses the liver biopsy, there will be no further need to proceed with antiviral therapy consideration. Clinician will:
 - i. Document counseling related to the refusal of the procedure and subsequent continued viremia and continue to see the inmate in the Chronic Care Clinic every 3 months.
 - ii. Document refusal for biopsy in the Release of Responsibility form, the EMR as well as in the Infectious Disease database, and
 - iii. Forward a copy of the declination of treatment to DPSCS/HQ Infection Control office.

H. If detainee is proposed for ANTIVIRAL THERAPY, the clinician will update the comprehensive medical case summary and contact the Regional Infection Control Coordinator/designee for assembly of supplemental casework.

1.) The Regional Infection Control Coordinator will assemble and review the Hepatitis C Treatment request packet for presentation at the next clinical panel review which will include:

- a. A comprehensive medical case summary
- b. A complete copy of all supporting documentation as listed on the checklist sheet
- c. A copy of the signed consent
- d. Any refusal for treatment
- e. Document any delays in testing reports or procedures that created any default in the time periods to be met under the protocol.

2.) The Site Medical Director or the site ID staff will document on the HCV Evaluation Work Sheet the date reviewed, his/her signature and forward the HCV request for antiviral therapy to the Regional Medical Director for treatment recommendation.

3.) The Regional Medical Director/designee will present the "post liver biopsy" cases to the DPSCS Clinical Panel within a period of time which should not exceed 15 days from the time the liver Biopsy report is received.

I. The DPSCS Clinical Panel will:

- 1.) Review submitted documentation for completeness.
- 2.) Review GI/ID opinion and Histology report.
- 3.) Communicate one of the following determinations:
 - a. Pending: more information needed,
 - b. Approved: Initiate treatment on site following recommendations of specialist consultant,

- c. Referred to GI or ID Specialist for concerns/further evaluation/treatment. Consultation presentation to the UM contractor for off site specialists should occur within 5 working days of the panel recommendations.
 - d. Denied: secondary to inappropriateness for antiviral treatment, continue to monitor in Chronic Care Clinic
- J. Following panel determination, -DPSCS Hepatitis C coordinator will inform Utilization and Pharmacy services within 48 hrs via e-mail.
- K. If antiviral drug therapy is to be initiated, the clinician will write medical orders and send to the Pharmacy vendor within 72 hrs.
 - 1.) A copy of the order will be sent to DPSCS Hepatitis C nurse.
 - 2.) A copy of the MAR indicating when therapy starts (first month only) will be sent to DPSCS Hepatitis C nurse.
 - 3.) Any refusal for HCV therapy will be documented in the medical record/ EMR of the inmate
 - 4.) All refusals for HCV treatment must be presented to the HCV panel for tracking and risk management.
 - 5.) Inmate will be required to sign a "Release of Responsibility" form indicating that she/he has refused therapy.
 - 6.) A copy of the "Release of Responsibility" form will be sent to the DPSCS Hepatitis Coordinator and the pharmacy vendor.
- L. Community Initiated HCV therapy continuation:
During the intake process, any inmates identified to be on HCV antiviral therapy will be referred immediately to the Medical Provider to assure continuity of treatment. The Medical Provider or designee will:
 - 1.) immediately obtain medical records from the community provider to verify the patient's treatment modality via release of information form signed by the inmate.

- 2.) document date of request for medical record in the patient 's medical record/EMR.
 - 3.) notify the Regional medical director and OIHS HCV Nurse /Medical director via e-mail with data regarding approval for continuation of community treatment medications for HCV disease including:
 - a. inmate's name
 - b. inmate's DOC number
 - c. community provider
 - d. genotype
 - e. Medications being used for HCV therapy continuation.
 - 4.) document OIHS permission to continue antiviral therapy.
 - 5.) complete a non formulary request to obtain a "bridge" order approval from the Regional Medical Director to continue HCV medications for 30 days.
 - 6.) present the case to HCV panel the next HCV panel meeting date.
 - 7.) following the panel's determination, DPSCS Hepatitis C coordinator will inform Utilization Management and the Pharmacy services within 48 hrs via e-mail:
 - a. inmate's name
 - b. inmate's DOC number
 - c. community provider
 - d. genotype
 - e. Medications being used for HCV therapy continuation
- M. Liver transplant considerations: Any HCV positive inmate who has been identified as a potential candidate for liver transplant or enters our system already on a liver transplant listing will be presented to the panel for evaluation and recommendations. DPSCS does not make the determination of candidacy for transplantation eligibility; however, the panel may recommend the following:
- 1.) Referral of inmate to UMMS transplant panel for further recommendations.

- 2.) On a case by case basis, consideration for parole as well as transport to a security based facility with 24 hour infirmity services will be made. The inmate will be placed on medical hold.

N. Palliative Care/Hospice

A living will shall be facilitated by medical/mental health. In the event a liver donor is not found or transplant is not an option and parole is denied, the inmate shall be counseled regarding options, living will, hospice care, etc...

- 1.) A designated relative or friend will be identified and assigned limited power of attorney to facilitate options in a living will with assistance from pastoral services.
- 2.) A copy of the living will shall be given to the inmate and placed in hard copy medical records and noted in EMR.

O. HBV/HCV co-infection:

Therapy is also provided to inmates who are HCV/HBV co-infected and these cases must be presented to the Hepatitis Panel for recommendations of treatment.

III. References:

- A. Mandell, Douglas and Bennett's Principles and Practice of Infectious Disease, fourth Edition, Volume I, 1995
- B. Federal Bureau of Prisons, Clinical Practice Guidelines for the Prevention and Treatment of Viral Hepatitis, October, 2005.
- C. Sulkowski MS, Thomas DL. Hepatitis C in the HIV-infected person. Ann Intern Med 2003; 138:197-207.
- D. Alvess C, Yee H et al. Practice guide, Management and Treatment of Hepatitis C Viral Infection: Recommendation From the Department of Veterans Affairs Hepatitis C Resource Center Program and the National Hepatitis C Program Office.
- E. Gastroentrology 2006; 101; 2360-2378

- F. Stradler D.B., Wright T et al. AASLD Practice Guidelines, Diagnosis, Management and Treatment of Hepatitis C. Hepatology 2004; 39; 1147-1171

IV. Rescissions: None

V. Date Issued: September 2005

Reviewed and revised : September 23, 2009

Patient Name			DPSCS NO:		Facility	
(LAST)	(First)	(MI)	SID NO:			
REVIEW/DOCUMENTATION OF EXCLUSIONARY CRITERIA						
YES	NO					
<input type="checkbox"/>	<input type="checkbox"/>	Age <18, or age >60 Age: _____				
<input type="checkbox"/>	<input type="checkbox"/>	Life expectancy less than 10 years				
<input type="checkbox"/>	<input type="checkbox"/>	Remaining incarceration time <24 months Rel. Date: _____				
<input type="checkbox"/>	<input type="checkbox"/>	History of solid organ transplant				
<input type="checkbox"/>	<input type="checkbox"/>	Known/documented history of autoimmune disease				
<input type="checkbox"/>	<input type="checkbox"/>	Adherence to any chronic care visits and/or medication adherence <80% _____ % Compliance (eg. Poor Hg A1c, TLTB RX, etc)				
<input type="checkbox"/>	<input type="checkbox"/>	Known/documented alcohol and/or illicit drug use within previous 12 months. (OMSR Verified) Date: _____				
<input type="checkbox"/>	<input type="checkbox"/>	Pregnancy				
<input type="checkbox"/>	<input type="checkbox"/>	AIDS CD4 <200; VL >50,000 copies				
<input type="checkbox"/>	<input type="checkbox"/>	Decompensated liver disease				
<input type="checkbox"/>	<input type="checkbox"/>	Decompensated Mental Health Condition				
<input type="checkbox"/>	<input type="checkbox"/>	Mental Health DX (or H/O DX): _____ Axis I <input type="checkbox"/> Axis II <input type="checkbox"/>				
HCV Pre-Test Counseling Conducted		DATE: _____	By: _____			
HCV Informed Consent Signed/Declined		DATE: _____	By: _____			
HCV Antibody Drawn		DATE: _____	By: _____			
HCV Post-Test Counseling Conducted		DATE: _____	By: _____			
Enrolled in Chronic Care Clinic		DATE: _____	By: _____			
HCV Patient Education Provided		DATE: _____	By: _____			
HCV Pt. Info Sheet Given		DATE: _____	By: _____			
If HIV status unknown:						
Date of HIV Test		DATE: _____	Results			
Vaccinations:						
Hepatitis A		DATE: _____	By: _____			
		DATE: _____	By: _____			
Hepatitis B		DATE: _____	By: _____			
		DATE: _____	By: _____			
		DATE: _____	By: _____			
Twinrix		DATE: _____	By: _____			
		DATE: _____	By: _____			
		DATE: _____	By: _____			
ID/GI consult		DATE: _____	By: _____			
HCV Viral Load Drawn		DATE: _____	By: _____			
General Screening Performed		DATE: _____	By: _____			
HCV Genotype testing		DATE: _____	TYPE: _____			
Risk Strat/TX Options Reviewed with Pt.		DATE: _____	By: _____			
DPSCS PANEL REVIEW FOR LIVER BIOPSY					Date Reviewed:	
Liver Biopsy Recommendation		YES	NO	DPSCS concurs		Comments
By ID/GI consult		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Signature _____
Referral to Site Medical Director/Site ID staff for Review					Date Reviewed: _____	
					Signature _____	
Referral to Regional Medical Director for Review					Not Appropriate for Therapy <input type="checkbox"/> Recommend Therapy <input type="checkbox"/>	
Date Reviewed:		Signature: _____				
Submission of Case to DPSCS Panel:		Date: _____		By: _____		
Received at DPSCS/HQ		Date: _____		By: _____		
Notification of Pt Transfer to		Date: _____		By: _____		
Region: _____						

[illegible]



DEPARTMENT OF PUBLIC SAFETY AND CORRECTIONAL SERVICES

DPSCS HEPATITIS C CLINICAL PANEL REVIEW

Patient Name	DPSCS NO:	Facility
(Last) (First) (MI)	SID NO:	
DPSCS Hepatitis C Clinical Panel Determination:		
<input type="checkbox"/> Pending: More information needed (see below) <input type="checkbox"/> Approved: Proceed with appropriate interferon/ribavirin protocol <input type="checkbox"/> Referred: to GI or ID Specialist for futher evaluation <input type="checkbox"/> Denied: Not Appropriate for Antiviral RX continue to monitor in CCC <input type="checkbox"/> Copy of liver Biopsy and Histology		
Recommendations/Reasons:		
DPSCS Medical Director Signature:	Date:	
DPSCS Infectious Disease Consultant Signature:	Date:	